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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,846	04/20/2004	Steven R. Binder	02558B-063710US	5304

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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04/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/828,846	Applicant(s) BINDER ET AL.	
	Examiner PABLO WHALEY	Art Unit 1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 February 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1-31.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
 13. ☐ Other: _____.

/John S. Brusca/
Primary Examiner, Art Unit 1631

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments filed 2/11/2008 are not persuasive for the following reasons.

Claims 1-5 and 11-31 remain rejected under 35 U.S.C. 103(a) as being obvious by Zimmerman et al. (Electrophoresis, 1995, Vol. 16, p.941-947), in view of Thompson et al. (Lupus, 1993, 2, p.15-19) and Kim et al. (IEEE Transactions on Pattern Analysis and Machine Intelligence, 1986, p.761-765), and further supported by Anderson et al. (WO/1999/039298; Filed 03/02/1999).

Applicant arguments filed 2/11/2008 that none of the above references teaches the limitations of the claims, in particular automatically applying a k-nearest neighbor process to indicate whether a test sample is associated with none, one or more of the claimed SADs, have been fully considered. However, Zimmerman teaches a procedure for comparison of autoantibody blots (i.e. data sets) comprising the statistical comparison of any group of staining patterns, e.g. those derived from patients with autoimmune diseases or normal controls, the identification of at least one of the samples that contribute most to the differences between such groups, and the determination whether an unknown individual sample belongs to a known group [Abstract]. Furthermore, their multivariate approach for classifying unknown samples is based on a continuum of "normal" and "diseased" sample sera, wherein each is described by variables representing a particular staining behavior [p.946, Section 4]. Thompson was relied upon as a teaching for patients with systemic lupus erythematosus (SLE) based on their autoantibody profile (Abstract). Kim was relied upon as a teaching for a fast k-nearest neighbor (kNN) search algorithm based on ordered partitions and applied to data samples (Abstract). Therefore, contrary to applicant's arguments, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the method of Zimmerman et al. using the SLE antibody profiles of Thompson et al., and the added feature of a "k-nearest neighbor" algorithm taught by Kim et al., where the motivation would have been to improve automated diagnosis of SLE with a more robust statistical "kNN" procedure [Zimmerman et al., Section 4]. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings in view of Anderson et al., who teach a decision-support computer system using neural network algorithms to classify and identify patterns in antibody data for disease diagnosis [WO/1999/039298; Filed 03/02/1999, Summary of the Invention].

Claims 6-10 and 22-24 remain rejected under 35 U.S.C. 103(a) as being obvious by Thompson et al. (Lupus, 1993, 2, p.15-19), in view of Kim et al. (IEEE Transactions on Pattern Analysis and Machine Intelligence, 1986, p.761-765) and Diamond et al. as applied to claims 1-5 and 11-14, above, and further in view of Kopecky (Design and Implementation of the Internet-Based Medical Expert System ToxoNet, 1999, p.1-153)

Applicant arguments filed 2/11/2008 that none of the above references teaches the limitations of the claims, in particular automatically applying a k-nearest neighbor process to indicate whether a test sample is associated with none, one or more of the claimed SADs, have been fully considered. However, Thompson teaches a distribution of autoantibody profiles in 117 SLE patients [Table I, below]. Profile data sets are provided that are not associated with any of the SADs required by the claims. Furthermore, Tables III and IV provide "negative" profiles indicative of datasets not associated with disease. Therefore, Thompson teaches reference data sets that include at least one reference data set associated with none of the specific SADs. Kim teaches a fast k-nearest neighbor (kNN) search algorithm based on ordered partitions applied to data samples (Abstract). Kopecky teaches an internet-based medical expert system (ToxoNet) for providing automated decision support to the clinician. Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to use the antibody profiles of Thompson et al. with the k-nearest neighbor searching algorithm of Kim et al. and the internet-based decision support system of Kopecky, where the motivation would have been to integrate autoimmune disease databases with a World Wide Web interface to provide remote automated decision support (Kopecky [1.1]), resulting in the practice of the instant claimed invention. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings in view of Diamond et al., who teach an automated decision support system combining computer-implemented methods and analysis of immunological data sets [Abstract] .

/Pablo S. Whaley/
Patent Examiner
Art Unit 1631